

## REMARKS

### **A. Status of the Claims**

Claims 9-22 were pending at the time of the Action. Claim 9 has been amended to incorporate the limitations of claims 12 and 13. Claims 11-13 have been canceled. Thus, claims 9 and 14-22 are currently pending. Because the amendment to claim 9 merely incorporates the limitations of previously examined claims 12 and 13, any new grounds for rejection cannot be based on Applicant's amendment. Thus, if any new grounds for rejection are raised in a subsequent Office Action, that Office Action cannot be made final.

### **B. The Claims Are Patentable Over Fuchs *et al.***

The Action rejected claims 9-22 under 35 U.S.C. § 102(b) as being anticipated or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Fuchs *et al.* (WO 01/97634 A1). Applicant traverses these rejections.

#### ***1. The Claims Are Novel Over Fuchs***

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP § 2131. The Action fails to establish that Fuchs teaches all of the elements of the current claims.

Current claim 9 is directed to a method of treating or preventing neurodermatitis or psoriasis in a subject comprising: obtaining a composition comprising a mare milk concentrate dried on a biologically inert, disperse matrix; and orally administering the composition to a subject. The Action does not identify any passages in Fuchs that expressly teach the use of a mare's milk concentrate dried on a biologically inert, disperse matrix for the treatment or prevention of neurodermatitis or psoriasis. To the extent that the Action is asserting that the current claims are inherently disclosed in Fuch's, it is the Examiner's burden to provide a rationale or evidence to show inherency. MPEP § 2112(IV). To establish inherency, the

extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Neurodermatitis and psoriasis are disorders resulting from an over-reactive immune response (*see e.g.*, Specification, p. 2, ln. 9-13 and p. 5, ln. 8-13). As noted in the Action, Fuchs discloses that dry concentrates of mare's milk have immunostimulatory properties. Since neurodermatitis and psoriasis are regarded as autoimmune diseases (*see* Specification, pages 1 to 7), a person of ordinary skill in the art would expect that the treatment of neurodermatitis and psoriasis would require immunosuppressive substances, not immunostimulatory substances. Thus, a person of ordinary skill in the art would not recognize an inherent disclosure of the presently claimed method in the Fuchs reference.

In view of the above, Fuchs does not expressly or inherently disclose the presently claimed method. Applicant, therefore, requests the withdrawal of this rejection.

## **2.     *The Claims Are Non-Obvious Over Fuchs***

The Action argues, in the alternative, that claims 9-22 are obvious over Fuchs. Applicant traverses this rejection.

To establish a *prima facie* case of obviousness, the Action must show: (1) some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) a reasonable expectation of success; and (3) the prior art reference teaches or suggests all of the claim limitations. One of ordinary skill in the art would not have been motivated to use nor have had a reasonable expectation of success in a method of treating or preventing neurodermatitis or psoriasis in a subject by orally administering a composition comprising a mare milk concentrate dried on a biologically inert,

disperse matrix to the subject, in view of the disclosure in Fuchs that a dried, mare milk concentrate has immunostimulatory properties (*see* Fuchs, p. 15).

A person of ordinary skill in the art would expect that the treatment or prevention of neurodermatitis and psoriasis would require immunosuppressive substances, not immunostimulatory substances. Thus, Fuchs disclosure that dried mare's milk concentrate has immunostimulatory properties actually teaches away from the presently claimed invention. A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness. *In re Gurley*, 27 F.3d 551, 554 (Fed. Cir. 1994).

Furthermore, in view of the reported immunostimulatory properties of the dried mare's milk concentrate, it is surprising and unexpected that its use would result in the treatment or prevention of neurodermatitis and psoriasis as demonstrated in the working examples of the present specification.

For the reasons set forth above, the current claims are non-obvious over Fuchs. Applicant, therefore, requests the withdrawal of this rejection.

### **C. Conclusion**

Applicant believes this to be a complete reply to the Office Action dated May 11, 2006, and respectfully requests favorable consideration of the claims in view of the amendments and statements contained herein.

The Examiner is invited to contact the undersigned attorney with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Date: October 11, 2006